REMARKS/ARGUMENTS

By the present proposed amendment, one (1) claim is amended and zero (0) claims are cancelled. Claims 47-48 and 51-61 are pending. No fees for claims are believed payable. Claim 61 is amended to change dependency only. Applicants submit that no new matter has been added by the present proposed claim amendments and no change in inventorship is believed to result. Entry of the proposed amendments is respectfully requested.

I. Objections to the Title and Abstract.

The Title and Abstract were objected to for allegedly not adequately describing the claimed invention.

Without acquiescing to the merits of the objection, and solely to expedite prosecution of the instant application, Applicants propose an amended Title and Abstract by way of the instant paper. Applicants submit that no new matter has been added by the present proposed amendments to the Specification. Accordingly, Applicants respectfully request that the objection to the Title and Abstract be reconsidered and withdrawn.

II. Rejection under 35 U.S.C. § 112 (second paragraph).

Claim 61 stands under 35 U.S.C. § 112 (second paragraph) as being indefinite. Specifically, the Office Action asserts that claim 61 depends from a cancelled claim.

Without acquiescing to the merits of the rejection, and solely to expedite prosecution of the instant application, Applicants have amended claim 61 to depend from claim 47. As such, claim 61 depends from a pending claim. Accordingly, Applicants respectfully request that the rejection of claim 61 under 35 U.S.C. § 112 (second paragraph) be reconsidered and withdrawn.

III. Rejection Under 35 U.S.C. 103.

Claims 47-48 and 51-61 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 98/30706 in view of Liu *et al.* (1992) *PNAS* 97(26): 283-292 ("*Liu*"). According to the Office Action, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to produce the construct of WO 98/30706 employing the T-cell epitopes of SEQ ID NOs: 3 and 4, as taught by *Liu* (Office Action at page 3). Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, the Office must first demonstrate that a prior art reference, or references when combined, teach or suggest all claim elements. See, *e.g., KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007); *Pharmastem Therapeutics v. Viacell et al.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007); *Abbott Laboratories v. Sandoz, Inc.*, 529 F.Supp. 2d 893 (N.D. Ill. 2007) and MPEP § 2143(A)(1). In addition to demonstrating that all elements were known in the prior art, the Office must also articulate a reason for combining the elements. See, *e.g., KSR* at 1741; *Omegaflex, Inc. v. Parker-Hannifin Corp.*, 243 Fed. Appx. 592, 595-596 (Fed. Cir. 2007) citing *KSR*. The Supreme Court in *KSR* also stated that that "a court ***must*** ask whether the improvement ***is more than*** the predictable use of prior art elements according to their established functions." *KSR* at 1740 (emphasis added). As such, in addition to showing that all elements of a claim were known in the prior art and that one of skill had a reason to combine them, the Office must also provide evidence that a reasonable expectation of success existed at the time the invention was made. MPEP 2143.02.

As is discussed in detail below, Applicants respectfully submit that the Office Action fails to articulate a reason for combining the construct of WO 98/30706 with the T-cell epitopes of *Liu*. Furthermore, no reasonable expectation of success existed at the time the present invention was made.

1. No articulated rationale for combining claim elements has been provided.

The Office Action states that "[o]ne of ordinary skill in the art at the time the invention was made would have been motivated to use the epitopes of Liu et al. because they were thought to be involved in the diabetogenic process and thus, suitable for use in the constructs of the instant claims." OA at 3. Applicants respectfully submit that this statement does not evidence an articulated reason for combining Liu and WO 98/30706. According to Liu, "***it is not clear*** which GAD peptides(s) can select for diabetic T Cells and cause the disease. It is ***possible*** that T cells specific for ***different autoantigenic peptides*** play different roles in the development of type 1 diabetes." Lui at 14601 (emphasis added). Therefore, according to Liu, the role of any of the various GAD or other potential autogenic peptides in type 1 diabetes was, at best, unclear at that time. The mere identification of a ***possibility*** that T cells specific for different autoantigens may play different roles in type 1 diabetes does not rise to the level of an articulated rationale for combining the peptides of Liu with the construct of WO 98/30706 under any of the exemplary

rationales found in the MPEP or under any other articulated rationale. As such, no *prima facie* case of obviousness exists.

2. No reasonable expectation of success has been established.

The Office Action is completely silent as to any expectation of success that one of skill in the art might have had at the time the instant invention was made, which, as is set forth above, is a required element of a *prima facie* case of obviousness. MPEP 2143.02. As such, the asserted *prima facie* case of obviousness fails.

Conclusion:

Applicants respectfully submit that the Office Action fails to articulate a reason for combining the construct of WO 98/30706 with the T-cell epitopes of *Liu* and that no reasonable expectation of success existed at the time the present invention was made. As such, the asserted *prima facie* case of obviousness must fail. Withdrawal of the instant rejection is therefore respectfully requested.

CONCLUSION

The application is believed to be in condition for allowance. Early and favorable considerations is respectfully requested. The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

Respectfully submitted,

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